Options for the future regulation of "low risk" products.

Consultation Paper

Response – 12th May 2017

Nestle Australia Ltd appreciate the opportunity to respond to the consultation paper on reforms to the options for the future regulation of low risk products.

Nestlé has the following comments to make on low risk registered non-prescription (OTC) medicines.

Nestlé supports in principle that well known OTC products that have a safe history of use and that are available for general sale could become eligible to become listable. Because of other ongoing consultations for listed medicines the future regulation of listed medicines and the indications and claims that will be permitted for listed medicines is unclear.

If currently registered medicines had a loss of claims that could be made or needed to add qualifiers to the indications that suggest a drop in efficacy when they changed to listed medicines, then Nestlé would not support this proposal.

The lower risk OTC products that Nestlé consider could be suitable to become listable are:

- Registered desensitising toothpastes
- Lozenges containing anti-microbial active ingredients for relief of sore throat
- Antacids containing carbonates, hydroxides, silicates and / or alginates.
- Menthol based inhalers
- Certain laxatives.

Changes in the classification of these products from registered to listed would mean that they are still manufactured to the same high level of GMP as they are currently. The change from a registered to listed category would reduce regulatory complexity and allow sponsors to more easily introduce changed or new product formulations or new pack types in response to consumer need.

In conclusion, Nestlé support in principle that certain lower risk OTC medicine products could become eligible to be listed, but only if the current indications and claims that these products have as registered products can continue to be made as listed products.

Nestlé's finals position would therefore depend on the outcome of other consultations that impact on the future regulation of listed medicines.